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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,007	11/28/2000	James L. Kurk	1416.30US01	7252

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EXAMINER

STAICOVICI, STEFAN

ART UNIT	PAPER NUMBER
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1732

14

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/724,007

Applicant(s)

KURK ET AL.

Examiner

Stefan Staicovici

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): rejection of claim 36 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is ~~(or will be)~~ as follows:Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1-11 and 29-37.Claim(s) withdrawn from consideration: None.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See attachment

## **ATTACHMENT TO ADVISORY ACTION**

### ***Response to Remarks***

1. Applicants' After-Final response filed April 30, 2003 (Paper No. 13) has been entered.

In view of Applicants' remarks the rejection of claim 36 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph has been withdrawn.

2. Applicants argue that because "Applicants did not amend any of the claims" then the Examiner's statement that "Applicants' amendment necessitated new grounds of rejection" in the Final rejection mailed December 4, 2002 (Paper No. 9) is incorrect and the Final rejection should be withdrawn (see page 7 of the After-Final response filed April 30, 2003).

In response, it should be noted that Applicants' amendment filed September 18, 2002 (Paper No. 8) added new claims 30-37 that included limitations *not previously presented* (emphasis added) and as such new ground of rejection was necessitated by the Applicants' addition of newly presented limitations in the added claims. Therefore, the "new grounds of rejection" was necessitated by Applicants' "newly added limitations" not presented for examination at the time of mailing the First Non-Final Action on June 18, 2002 (Paper No. 6). Further, it should be noted that under MPEP §706.07(a), if "information is submitted in an information disclosure statement during the period set forth in 37 CFR 1.97(c) with a fee, the examiner may use the information submitted, e.g., a printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended." Applicants submitted an Information Disclosure Statement on July 16, 2002 (Paper No. 7),

whereas a First Non-Final Action was mailed about a month earlier on June 18, 2002 (Paper No. 6).

Applicants argue that “this submission of dependent claims did not require any further searching other than that searching which is ordinarily performed to fill the gaps between Office Action and Applicants’ response (see page 7 of the After-Final response filed April 30, 2003). In response, it should be noted that:

(a) Under MPEP §706.07(a), a “second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).” In this case, Applicants’ amendment filed September 18, 2002 (Paper No. 8) added new claims 30-37 that included limitations *not previously presented* (emphasis added) and as such new ground of rejection was necessitated by the Applicants’ addition of newly presented limitations in the added claims.

(b) Applicants submitted an Information Disclosure Statement on July 16, 2002 (Paper No. 7), whereas a First Non-Final Action was mailed about a month earlier on June 18, 2002 (Paper No. 6).

Therefore, in view MPEP §706.07(a), whether a new search is or is not required is not a matter of consideration in determining whether a “second or any subsequent actions on the merits shall be final.”

Applicants argue that the mandrel of Jansen *et al.* ('113) "is provided with planar surfaces whereas the mandrel set forth in Applicants' claim 1 is provided with contoured surfaces" (see page 9 of the of the After-Final response filed April 30, 2003). However, as described in column 6, lines 59-66, although Jansen *et al.* ('113) teach that "surfaces 5 are *substantially* plane" (emphasis added), Jansen *et al.* ('113) specifically teach that said "surfaces 5...are slightly curved toward the upper end of the dip mold". As such "surfaces 5" are *not* (emphasis added) completely planar as Applicants' reading of Jansen *et al.* ('113) implies, because a *desired* (emphasis added) curvature is included in the mandrel of Jansen *et al.* ('113) and as such form "contoured surfaces". Since, Applicants have not numerically defined a "contoured surface", it is submitted that Jansen *et al.* ('113) teaches "contoured surfaces."

Applicants argue that in Jansen *et al.* ('113) "the free edge of the leaflets does not extend beyond the peak of post 6" and in Pierce *et al.* ('127) the "free edge of the leaflet (40) is along the middle of the top of shim 35" (see pages 9 and 11 of the of the After-Final response filed April 30, 2003). First, it should be noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Specifically, as noted above, Jansen *et al.* ('113) teach a mandrel (7) having a plurality of ridges containing therebetween contoured surfaces (5) for forming polymer leaflets of a heart valve (valve prostheses) and further including an edge separating a top flat surface (8) from said contoured surfaces (5), said edge corresponding to free edges of said heart valve (valve

prostheses) (see Figure 1). Further, as shown in Figure 3, Jansen *et al.* ('113) show that the free edge of the leaflets extend beyond the post (6) and as such correspond to the edge of the top surface of the mandrel.

Pierce *et al.* ('127) teach a top surface (40) formed by shims (35) that define an edge separating the contoured surfaces (see Figures 10 and 11), said edge being formed at the intersection of the leaflet, whereas the shim acts as an "edge" for the mandrel surface. As shown in Figure 12 of Pierce *et al.* ('127) the shim acts as an "edge" for the mandrel surface and forms the free edge of separated leaflets. It should be noted that whether a processing step is required to separate the leaflets is a mere functional aspect of using the mandrel and does not provide patentability to the mandrel tool.

Applicants argue that NL 1008349 (Bosch) teaches a "two piece mold, not a mandrel," that does not include "contoured surfaces, a mandrel edge which corresponds to the free edge of the leaflets or an edge that separates the top surface and the contoured surfaces" (see page 10 of the of the After-Final response filed April 30, 2003). However, as shown in Figure 8A of NL 1008349, mandrel (81) includes a plurality of ridges containing therebetween contoured surfaces for forming polymer leaflets of said heart valve (valve prostheses) and further including an edge separating a top surface from said contoured surfaces, said edge corresponding to free edges of said heart valve (valve prostheses) (see Figure 8A). Further, it should be noted that although a mold (82) is also included, the "transitional term 'comprising', which is synonymous with 'including,' 'containing,' or 'characterized by,' is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Genentech, Inc. v. Chiron Corp., 112 F.3d 495,

501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). Furthermore, it should be noted that in a claim drawn to an apparatus/tool, it is the structural limitations that determine patentability of said apparatus/tool and “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Therefore, Applicants’ argument that NL 1008349 (Bosch) teaches a “two piece mold” rather than a “mandrel” is not persuasive because the mandrel (81) of NL 1008349 (Bosch) teaches a plurality of ridges containing therebetween contoured surfaces for forming polymer leaflets of said heart valve (valve prostheses) and further including an edge separating a top surface from said contoured surfaces, said edge corresponding to free edges of said heart valve (valve prostheses) (see Figure 8A).

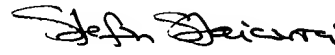
### ***Conclusion***

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stefan Staicovici, Ph.D. whose telephone number is (703) 305-0396. The examiner can normally be reached on Monday-Friday 8:00 AM to 5:30 PM and alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Richard D. Crispino, can be reached at (703) 308-3853. The fax phone number for this Group is (703) 305-7718.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

 5/15/03  
**STEFAN STAICOVICI, PHD**  
**PRIMARY EXAMINER**

AU 1732

May 15, 2003